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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,333	08/29/2001	Christopher M. Angelucci	8932-546	7696

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/942,333	Applicant(s) ANGELUCCI ET AL.	
	Examiner Jessica R. Baxter	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirabayashi et al ("contact of hydroxyapatite spacers with split processes in double-door laminoplasty for cervical myelopathy" Journal of Orthopaedic Science, 1999.) in view of Ford et al (U.S. Pat. No. 6,511,509).

Hirabayashi et al (hereafter "Hirabayashi") discloses the development and optimization of implants for double-door laminoplasty, wherein the resulting implants have angled surfaces clearly within the claimed range of "about 50 to about 70 degrees." It is also noted that the Hirabayashi implants were developed to solve the same problem as disclosed in the instant invention. However, Hirabayashi does not specifically disclose: the implant as having a substantially hollow portion; being formed from metal, polymer, or bone allograft material comprising the cross-section of a donor bone having an intermedullary canal;

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elliptical or circular shape', the specifically claimed width and depth dimensional ranges; surface projections; channels for use with distractor pliers; or a hollow suture attachment podion. Ford et al teaches textured bone allografts for use in a wide variety of treatments for patients suffering from defects caused by congenital anomaly, disease, or trauma, including large column defects and spinal defects. Among the many exemplary embodiments cited by Ford are textured trapezoidal wedges. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the basic inventive concept of Hirabayashi with the teachings of Ford to produce the applicants claimed invention, i.e. a bone allograft implant for use in a double-door laminoplasty having the bone engaging portions angled at about 50 to about 70 degrees, and further comprising all the claimed secondary features related to size, shape, surface projections, choice of materials, etc., since the design of all claimed secondary features are well within the skill level of one of ordinary skill in the art of orthopedic implant design, e.g. a biomechanical engineer.

The courts have concluded that there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). Also, references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969).

The courts have additionally concluded that a change in dimension, degree, size, shape, etc. without special functional significance is not patentable. Research Corp. v. Nasco Industries, Inc., 501 F2d 358', 182 USPQ 449 (CA 7), cert. denied 184 USPQ 193; USLW 3359 (1974), In re Rose, 105 USPQ 137, and In re Aller et al., 105 USPQ 233.

Response to Arguments

3. Applicant's arguments filed 11 April 2006 have been fully considered but they are not persuasive.

4. Applicant argues that the angles are not disclosed in Hirobayashi et al. However, in the Figures 1a and 1b, it is clear that the discloses spacer are within the claimed ranges. These figures are to scale since they are pictures of the actual spacer. In addition, applicant does not disclose any particular reason for having these angles. Therefore, Hirabayashi could be modified to include these angles if these angles were not already disclosed since discovering an optimum range or workable range only involves routine skill in the art.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R. Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



jrb

Jessica R Baxter
Examiner
Art Unit 3733



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER